(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

September 12, 2007
Second Floor
Conference Room 2

Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463

CALL TO ORDER: The meeting was called to order at 9:20AM.

PRESIDING: Bobby Ison, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
John O. Beckner
Willie Brown
Gerard Dabney
Jennifer H. Edwards
David C. Kozera
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Ralph Orr, Program Manager, Prescription Monitoring Program
Howard M. Casway, Senior Assistant Attorney General
Emily Wingfield, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Sharon Davenport, Administrative Assistant

INTRODUCTIONS AND QUORUM: Board members and staff introduced themselves. Mr. Ison welcomed Gerard Dabney, newly-appointed citizen member of the Board of Pharmacy replacing Diane Langhorst. With ten members present, a quorum was established.

APPROVAL OF AGENDA: With no changes to the agenda, the agenda was approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for June 12, 2007 and July 26, 2007. With no changes to the minutes, the minutes were approved as presented.

PUBLIC COMMENTS: Mr. Ison called for public comments and none were given at this time.

DHP DIRECTOR'S REPORT: Ms. Wingfield gave a brief report on behalf of Sandra Whitley Ryals, Director, DHP, who was unable to attend the Board meeting due to conflicting schedules. Ms. Wingfield welcomed the Board

to the new building and also welcomed Mr. Dabney on behalf of the Department and Ms. Ryals. She explained to the Board that due to current revenue shortfalls, agencies were being asked to cut budgets, and that one area that would be further restricted is out-of-state travel. Ms. Wingfield stated that new Board member training was being planned and a date would be forthcoming.

LEGISLATION UPDATE: Ms. Yeatts provided a summary of the three legislative proposals being submitted for approval on behalf of the Board of Pharmacy. The first proposal is to remove from statute the specific expiration dates for renewal of licenses in order to allow the Board, in regulation, to stagger some expiration dates to better control staff workload. The second proposal is to seek authority for the Board to require topic-specific continuing pharmacy education programs with appropriate prior notice to pharmacists. The third proposal is the annual scheduling of controlled substances legislation to have Virginia controlled substances schedules conform to federal schedules.

REGULATION UPDATE: Ms. Yeatts provided a summary of ongoing regulation processes.

- PPG — She stated that the fast track public participation guidelines regulations were final effective August 25, 2007.
- NOIRA-periodic review — She stated that the Board's NOIRA for changes to its general regulations pursuant to the recent periodic review had been published and the public comment period closed as of September 5, 2007.
- Collaborative Practice — Final regulations are at the Governor's office awaiting approval for publication.
- Pedigree Regulations — The public comment on the proposed regulations ended August 10, 2007, and the Board will be acting on the comments and adopting final rules later in the agenda.
- Petition for Rulemaking — The Board received and published a petition for rulemaking from Sherry Fortune requesting that the Board allow an automated dispensing device in a long term care facility to be used only for stat and emergency box drugs and without a pharmacist review of new orders needed prior to removing drugs for administering. Ms. Fortune has since withdrawn the petition stating that she planned to comply with the current regulation.
- Petition for Rulemaking — The Board received and has sent for publication a petition for rulemaking from Ken Dandurand on behalf of MedNovations, Inc. to allow a non-resident pharmacy to use pharmacists not licensed in Virginia to provide outsourced pharmacy services to Virginia pharmacies. Comment on this petition will be received until

October 31, 2007. The Board may act on the petition at its December meeting.

FINAL PEDIGREE REGULATIONS:

The Board reviewed the current proposed regulations for establishment of a pedigree system and public comment received during the comment period. The Board received comments from Anne Leigh Kerr, Pharmaceutical Research and Manufacturers of America (PhRMA); Elizabeth Gallenagh, Healthcare Distribution Management Association (HDMA); Martha Russell, Cardinal Health; and Michelle Cope, National Association of Chain Drug Stores (NACDS).

- ADR to ADR to office-based practitioner

HDMA requested an addition to 18 VAC 110-50-160 to include distribution from a manufacturer to an Authorized Distributor of Record (ADR) to one additional ADR then to an office based healthcare practitioner for the purpose of administering or dispensing to patients as a distribution for which a pedigree is not required.

Motion:

A motion was made and passed, to add language to 18 VAC 110-50-160 to exempt manufacturer to ADR to ADR to office-based practitioner from pedigree requirements. (Motion by Edwards, Second by Beckner)

- "Drop shipment"

There were comments from Cardinal and HDMA requesting different definitions of this term than in the proposed regulations.

- "Co-licensed partners" or "co-licensees"

There were requests from Cardinal and HDMA requesting that this term be added to definitions and included in 18 VAC 110-50-160 as a form of distribution not susceptible to counterfeiting, and include in the term "drop shipment". There was significant discussion related to the appropriate definition, the definition given by Cardinal versus the definition in the NABP model regulations. Ms. Russell stated that this was discussed at length during the promulgation process by the committee and these same interested parties, and that a determination was made at that time that a co-licensee was a secondary manufacturer of a product and, therefore, any distribution from a co-licensee would be considered distribution from a manufacturer and would be within the normal chain of distribution. For this reason, the term was deemed not necessary and not included in the proposed regulations.

Motion:

A motion was made and defeated, with a vote of 8 to 2, to add a definition of "co-licensee", as defined in the NABP model regulations, to the Board's final regulations and insert the term where appropriate in the regulations. (Motion by Abernathy, Second by Ross)

- "Authentication"

The Board reviewed comments by Cardinal related to authenticating a pedigree. Cardinal had asked that a definition be

added as well as an introductory paragraph establishing a requirement for authentication in 18 VAC 110-50-180. After discussion, the Board determined that a definition was not needed because everything in the definition offered by Cardinal was also listed in the paragraph suggested to be added to 18 VAC 110-50-180.

Motion: **A motion was made and passed, to add a new paragraph A to 18 VAC 110-50-180 that reads "Each person who is engaged in the wholesale distribution of a drug, who is provided a pedigree as specified in 18VAC110-50-160 and attempts to further distribute that drug, shall affirmatively verify before any distribution of a prescription drug that each transaction listed on the pedigree has occurred." (Motion by Beckner, Second by Edwards)**

- General comment to adopt without change

The Board reviewed the comment by NACDS to adopt the proposed regulations without change.

- Add a "returns" section

Cardinal requested that the Board add a separate section to further clarify when a product could be "returned" without requiring a pedigree. Mr. Casway advised that applicability of returns of pharmaceutical products was already specified in the statute, and any expansion of allowable returns without a pedigree could be in conflict with law. There was discussion that returns to a third party returns processor provided the returns were for the purpose of proper disposal and not for further sale for use by the public would not constitute wholesale distribution by law in Virginia, and not require a pedigree.

- Clarification of authentication requirement

PhRMA requested that the Board insert clarifying language in 18 VAC 110-50-180 A (will now be 18 VAC 110-50-180 B), to ensure that a manufacturer or wholesale distributor would only have to provide authentication information for those distributions actually conducted by that manufacturer or wholesale distributor.

Motion: **A motion was made and passed, to add the phrase "only for those applicable transactions outside the normal chain of distribution conducted by that manufacturer or wholesale distributor" in 18 VAC 110-50-180, now paragraph B. (Motion by Yi, Second by Kozera)**

Motion: **A motion was made and passed, to adopt as final regulations the proposed regulations as amended by the Board today. (Motion by Beckner, Second by Yi)**

SANCTION REFERENCE: The Board reviewed the sanction reference manual and worksheet that had been developed for use by informal conference committees in determining sanctions by VisualResearch, Inc. A committee of the board met in July, reviewed the original

worksheet that had been developed several years ago, and made several modifications to the document. Neal Kauder, President of VisualResearch, was present to answer questions of the Board.

Motion: **A motion was made and passed, to adopt the manual and worksheet as a Board guidance document and to begin using this tool in informal conferences. (Motion by Ross, Second by Brown)**

INSPECTION COMMITTEE UPDATE: Ms. Russell stated that the inspection committee met on July 26th and began the task of reviewing the inspection reports and identifying deficiencies for which the immediate consent order process could be used. She stated that the committee had also determined that these immediate consent orders in most cases should hold the pharmacy permit as the respondent rather than the PIC, staff pharmacist, or owner specifically. She advised that this committee would need to meet probably several more times before it was ready to make a recommendation to the full Board, but the goal would be to make a recommendation possibly by the March 2008 meeting.

TECHNICIAN RESPONSIBILITY IN DISPENSING ERROR CASES: Ms. Russell explained that prior to registration of pharmacy technicians; the Board held only the checking pharmacist responsible for not assuring accuracy in cases involving dispensing errors, and when the registration process was initiated for pharmacy technicians, there was still sentiment on the part of the Board to only docket a case against the pharmacist. She stated that the Enforcement Division is receiving cases or noting in the investigation of cases that a pharmacy technician is identified as contributing to an error. She asked the Board to provide guidance as to whether to docket a case against both the pharmacy technician and the checking pharmacist in these type cases. After discussion, the Board, by consensus, agreed that cases should be docketed against both.

UPDATE GUIDANCE DOCUMENT RELATED TO UNREGISTERED PHARMACY TECHNICIANS: Ms. Reiniers-Day requested that, while the Board was discussing pharmacy technician cases, that it also discuss its previous guidance for issuance of a Confidential Consent Order (CCA) in cases where it is discovered that a person is performing pharmacy technician tasks without being registered with the Board or in an approved training program within the time limits for such training. Ms. Reiniers-Day suggested that the Board may want to consider increased sanctions for these cases since the requirement for technician registration has been in place over three years and pharmacists should be aware of the requirements, yet the Board is still receiving a number of these cases. There was some question as to jurisdiction over an unregistered person. Ms. Russell informed the Board that in most cases the unregistered persons performing technician tasks applied for registration and became

registered almost immediately once informed that they could not continue working as a pharmacy technician without being registered, so the Board then has jurisdiction to take disciplinary action. Most are already eligible for registration when the problem is discovered, but have just not yet made application. The Board agreed that it was time to move beyond the CCA for these cases and discussed appropriate sanctions.

Motion: **A motion was made and passed, to authorize staff to offer a pre-hearing consent order in these cases to both the pharmacy technician and the PIC, with the sanction of a reprimand to both and monetary penalty of $50 for the pharmacy technician and $250 for the PIC. (Motion by Beckner, second by Yi)**

ISSUE OF SCHEDULE II PRESCRIPTIONS AND TWO PRESCRIPTION NUMBERS:

Ms. Russell stated that staff is frequently asked how to handle the dispensing of a Schedule II prescription in which a patient wants a portion billed to a third party and to pay cash for the remainder when the pharmacy computer system will not then indicate the dispensing of the total amount under the same prescription number. Some pharmacies have a method for working around the problem by giving the one prescription two different prescription numbers and dispensing each partial amount under the two numbers. There was significant discussion as to whether this is allowed; on the side of allowing this practice, there is the fact that a prescription number is not required by law, the hard copy record would show that the prescription was really only one prescription and not partially dispensed, a lot of dispensing software could not accommodate a split billing transaction or pharmacists did not know how to do it. On the side of not allowing this practice, the data submitted to the Prescription Monitoring Program (PMP) is not correct, the hard copy is not really the official dispensing record any longer, and the label may show the incorrect quantity if all the drug is put in one vial or, if using two labels, it will look as though two prescriptions were filled. The Board responded that the official dispensing record for the pharmacy would have to accurately reflect one prescription and the total quantity dispensed on that date for that one prescription and must otherwise meet any requirements of law to include accuracy of reporting to the PMP.

DROP BOXES:

Ms. Russell stated that staff has received requests from pharmacies that want to install a drop box for patients to leave new prescriptions after pharmacy hours. There was significant discussion related to security, location and access. The consensus of the Board was to allow this practice with some guidelines to ensure the security of the prescriptions and that patients would not be able to leave containers which contain drugs to be refilled. Ms. Russell offered to draft a guidance document to be considered at the December meeting and the Board agreed.

STAMPS FOR INITIALS:

Ms. Abernathy requested that the Board determine if initial stamps could be used for records requiring the initials of the "checking" pharmacist rather than handwritten initials which are frequently illegible. She stated that at her hospital, they had a policy in which pharmacist had stamps containing all three initials, so that the checking pharmacist could be more easily identified. She stated she found with hand initials, usually the pharmacist only used two initials, she has pharmacists with the same two initials, and after someone has to initial a hundred items in a day the checking pharmacist could often not be determined. She stated the stamp system worked well. It was discussed that stamps could be stolen and used by someone else or the pharmacist could give a pharmacy technician his stamp and not really check. These concerns were countered with the fact that a pharmacy technician could easily copy the hand initials of the pharmacist, and that this was not so different than a pharmacist's initials in a computer system being used by someone else.

Motion:

A motion was made and passed, to allow the use of stamps by pharmacists on records requiring the pharmacists' initials. (Motion by Beckner, second by Ross)

NEWSLETTER TOPICS:

Staff asked if the Board members had any ideas for the upcoming Board newsletter. The Board stated that some of the decisions made at this meeting should be included such as the increase sanction for not registering pharmacy technicians, pharmacy technicians being held jointly accountable for dispensing errors, the use of stamps for initials, reminders about upcoming renewals and CE requirements particularly for pharmacy technicians.

BOARD OF HEALTH PROFESSIONS REPORT:

Ms. Edwards stated that she will attend her first Board of Health Professions meeting on September 25, 2007, and will have a report for the December meeting.

EXECUTIVE DIRECTOR'S REPORT:

- NAPLEX SUSPENSION UPDATE

Ms. Russell gave an update on the NAPLEX suspension, stated that NABP is working diligently to have the examination back online by November 1, and is hopeful it will meet that date. She stated that at the time of suspension of the NAPLEX, Virginia had 65 applicants who had not yet taken it.

- NEW EMPLOYEES

Ms. Russell stated that the Board has two new part-time employees assisting with various functions. Ms. Russell introduced Sharon Davenport who will be handling Board meeting matters including contacting Board members related to meeting schedules and travel vouchers. Virginia Davis is assisting the Board with a special project involving preparing the Board's files to be scanned for record retention.

- UPCOMING MEETINGS

Ms. Russell stated that she will be attending the NABP Fall conference next week in Arlington, VA, and the District II meeting in October in Wilmington, DE, as part of her NABP responsibilities. Mr. Ross and Mr. Yi will also be attending the Fall Conference. Due to travel restrictions and because there had been no requests, no Board members are attending the District II meeting at Board expense. Ms. Edwards stated that she will be attending on behalf of her employer.

- DISCIPLINARY PROGRAM UPDATE

Ms. Reiniers-Day presented the Board's disciplinary caseload report and stated that as of September 11, 2007, 208 cases were at the enforcement level, 55 cases were at the probable cause level, 6 cases were at the informal conference level, 3 cases were at the formal hearing level, 34 cases were at the APD level, 28 cases had either a Confidential Consent Agreement or pre-hearing Consent Orders pending for a total of 334 cases. Further, there were 249 cases at the Compliance Tracking level.

- LICENSING PROGRAM UPDATE

Ms. Juran presented the Board's licensing report and stated that the Board has issued approximately 800 licenses since the June 12, 2007, board meeting. The Board has issued 282 pharmacists licenses, 438 pharmacy technician registrations, 28 physician selling controlled substances licenses, 27 pharmacy permits, and 16 nonresident pharmacy registrations. Also, she stated that there has been concern regarding whether licensees know how to access proposed regulatory changes as it is proceeds through the development processes. Therefore, staff will research whether a Notice of Intended Regulatory Action may be posted directly to the Board's website. If not, it will be determined if information may be posted on the Board's website under the "FAQ" (Frequently Asked Questions) section which would give instructions on how to readily access proposed regulatory information by either accessing state websites such as Town Hall, or through receiving notifications via one of the notification lists. Lastly, Ms. Juran mentioned that the next e-newsletter will be published in November 2007.

- PMP UPDATE

Mr. Orr reported on the PMP program. The Prescription Monitoring Program (PMP) now holds over 15.9 million records with about 1 million records being added each month. Mr. Orr discussed the number of registered users of the PMP; over 1000 total, with just over 300 pharmacists registered. He noted that, to date in 2007, the PMP processed over 13000 requests for information compared to 6333 in all of 2006. Mr. Orr stated that while the workload is increasing, response time still averages less than 30 minutes. He updated the Board on the new project the PMP has undertaken working with Virginia Commonwealth University's School of Medicine. The project is to develop a web-

based module training program on pain management practices, laws and regulations and the role of the PMP. The project will complete testing in September/October 2007 with the unveiling of the website on November 16, 2007. Mr. Orr invited the Board members to attend the Fall Conference being sponsored by the PMP on November 16, 2007, at the Perimeter Center.

APPOINTMENT OF COMMITTEES

Mr. Ison appointed standing and ad hoc committees through June 30, 2008. The committee appointments are included as Attachment 1.

MEETING DATES

The calendar for full Board meetings has been set. There will be a Regulation Committee meeting on October 10, 2007. Dates for the CQI Committee, Drug Disposal Committee, and Inspection Committee will be set based on member and room availability, and the dates emailed to Board members. Mr. Beckner stated that Ukrops is having a pilot drug collection day at the Brook Run store on Tuesday, September 25th from 10AM until 2PM. He has coordinated with Lynn Rubenstein to be there. Mr. Beckner stated that after this trial run, he expects to have helpful information for the committee in developing a template for pharmacies that want to hold these programs.

ADJOURN:

With all business concluded, the meeting adjourned at 12:30 p.m.

Elizabeth Scott Russell
Executive Director

Bobby Ison, Board Chairman

Date

VIRGINIA BOARD OF PHARMACY
2007-2008

STANDING COMMITTEES

REGULATION	EXAMINATION	ITEM REVIEW	PILOT PROGRAM	SPECIAL CONFERENCE
Bobby Ison, Chair Dave Kozera Willie Brown Gill Abernathy Mickey Stredler **Alternates:** Citizen: Gerard Dabney Licensee: John Beckner any other Board member	Jennifer Edwards Brandon Yi John Beckner Mickey Stredler Scotti Russell	Nan Dunaway Jennifer Edwards Vicki Gwaltney Garrison Caroline Juran Sammy Johnson Scotti Russell	Bobby Ison, Chair John Beckner **Alternates:** Any pharmacist board member	Alternate between: Leo Ross Dave Kozera Jennifer Edwards Brandon Yi **Alternates:** Mickey Stredler Any other board member

AD HOC COMMITTEES

CQI	INSPECTIONS	DRUG DISPOSAL		
Gill Abernathy, Chair John Beckner Mickey Stredler Jennifer Edwards Vicki Garrison Sammy Johnson	John Beckner, Chair Leo Ross Brandon Yi Mickey Stredler Bobby Ison Vicki Garrison Sammy Johnson	Dave Kozera, Chair Brandon Yi Jennifer Edwards John Beckner Tim Musselman		